CERTIFICATE OF MAILING BY EXPRESS MAIL

I hereby certify that the attached Petition to Revive an Unintentional Abandonment under 37 C.F.R. §1.137(b), Exhibit A (10 pages), Fee Transmittal for FY 2004, check for $665.00, Postcard, and this Express Mail Mailing Certificate are being deposited on the date indicated below with the United States Post Office in an envelope addressed to:

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Diane L. Marshall
Signature

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

[X] Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 665.00

Complete if Known	
Application Number	09/676,380
Filing Date	9/29/2000
First Named Inventor	Baron, A., et al.
Examiner Name	Andres, J.
Art Unit	1646
Attorney Docket No.	99-057

METHOD OF PAYMENT *(check all that apply)*

[X] Check [ ] Credit card [ ] Money Order [ ] Other [ ] None

[X] Deposit Account:

Deposit Account Number: 501317

Deposit Account Name: Debra M. Parrish, PC

The Director is authorized to: *(check all that apply)*

[ ] Charge fee(s) indicated below [X] Credit any overpayments

[XX] Charge any additional fee(s) or any underpayment of fee(s)

[ ] Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below	Fee Paid
Total Claims		-20** =		X =
Independent Claims		- 3** =		X =
Multiple Dependent				=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) Petition to Revive 665.00

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 665.00

SUBMITTED BY				(Complete *(if applicable)*)	
Name (Print/Type)	Debra M. Parrish	*Registration No. (Attorney/Agent)*	38,032	*Telephone*	412-561-6250
Signature				*Date*	9-13-04

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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09-15-04

DAC ITW A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit 1646 :

In re application of :

ANDRE T. BARON, et al. :

Serial No. 09/676,380 :

Filed September 29, 2000 :

Examiner: Janet L. Andres :

SOLUBLE EPIDERMAL GROWTH FACTOR RECEPTOR-LIKE PROTEINS AND THEIR USES IN CANCER DETECTION METHODS

Pittsburgh, Pennsylvania
September 13, 2004

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

PETITION TO REVIVE AN UNINTENTIONAL ABANDONMENT UNDER 37 C.F.R. § 1.137(b)

The Applicant respectfully submits this Petition to Revive the above-captioned Application, pursuant to 37 C.F.R. § 1.137(b), stating as follows:

1. After receiving the July 29, 2003 final office action rejecting all the outstanding claims, Applicants, through their attorney, had a telephone conference with the Examiner to determine whether an amendment would put the claims in a condition for allowance.

2. Applicant filed an Amendment and Response to Final Office Action in connection with the above-captioned Application.

3. On March 11, 2004, after the telephone conference, the Examiner accepted an amendment which overcame the basis of rejection of some of the claims.

4. The Examiner's March 11, 2004 advisory communication indicated that certain claims were allowed, other claims were rejected, and other claims were objected to.

5. Based on this communication, Applicants believed that the Examiner had allowed the claims that had been discussed or had withdrawn the Final Office action and that communication should be treated at the final. The Examiner invited an Amendment to overcome the objected to claims to remove their dependency from a rejected claim.

6. The March 11, 2004 communication indicated that there was a six-month reply period from the final office action. Because the March 11, 2004 communication was more than six months after the July 2003 Final Office action, it did not seem logical that a new response period had not begun.

7. In either event, the Applicant believed that the Examiner had withdrawn the final basis of rejection based on its communication with the Examiner. As noted above, the March 11, 2004 communication indicated the allowance of some of the claims.

8. It was only upon receipt of the Notice of Abandonment and a subsequent telephone conference with the Examiner, that Applicants and the Examiner realized that the Examiner had erroneously indicated in the March 11, 2004 communication the allowance of withdrawn claims and not the claims the Applicant had discussed with the Examiner.

9. Applicant also noted that the Examiner inadvertently cited Applicants' response as one of the bases of rejection for the rejected claims.

10. To the extent that the absence of a response in connection with Applicant's Amendment and Response to Final Office Action gives rise to the possibility of abandonment of the above-captioned Application, any such abandonment was unintentional.

11. Applicant's Amendment in response to the Final Office Action, as invited by the Examiner, has been filed contemporaneously and a copy of this Amendment attached hereto as Exhibit A.

12. The appropriate petition fee of $665.00 for a small entity (statement previously filed) required under 37 C.F.R. § 1.17(m) is also enclosed. To the extent the unintentional abandonment is due to Examiner error, Applicants request a waiver of the fee.

WHEREFORE, the Applicants respectfully request revival of the above-captioned Application, to the extent necessary, to file the enclosed amendment.

Respectfully submitted,

PARRISH LAW OFFICES

By _____

Debra M. Parrish, Esq.,
Attorney for Applicants
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Examining Group 1646
PATENT APPLICATION
Serial No. 09/676,380
Atty. Docket No. 99-057

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit 1646 :

In re application of :

ANDRE T. BARON, et al. :

Serial No. 09/676,380 :

Filed September 29, 2000 :

Examiner: Janet L. Andres :

SOLUBLE EPIDERMAL GROWTH FACTOR RECEPTOR-LIKE PROTEINS AND THEIR USES IN CANCER DETECTION METHODS

Pittsburgh, Pennsylvania
September 13, 2004

AMENDMENT

Box NON-FEE AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Final Office Action of July 29, 2003, January 29, 2004 telephone conference, the March 11, 2004 advisory action, and the September 10, 2004 telephone conference, in the above-identified application, and pursuant to 37 C.F.R. 1.116. please amend the above-identified application as follows:

EXHIBIT A

IN THE CLAIMS:

Amend Claim 18 to read:

Claim 18 (amended): An assay for determining the concentration of epidermal growth factor receptor in a biological sample from a female patient, the assay comprising:

a) obtaining a biological sample from the female;

b) contacting an amount of a first purified antibody that specifically reacts with a first epitope of the extracellular ligand binding domain of sErbB1 with the biological sample to be tested, wherein the first purified antibody is modified with a first labeling moiety;

c) contacting the sample with an amount of a second purified antibody that specifically reacts with a second epitope of the extracellular ligand binding domain of sErbB1, wherein the second purified antibody is modified with a second labeling moiety, and wherein the second purified antibody does not competitively inhibit the binding of the first purified antibody;

d) detecting the co-presence of the first and second labels to determine the concentration of the epidermal growth factor receptor complexed with the antibodies;

wherein one of the antibodies is chosen from the group consisting of: MAb R.1 and antibodies which competitively inhibit the binding of MAb R.1 to ErbB1; and wherein the other antibody is chosen from the group consisting of MAb 528 and antibodies which competitively inhibit the binding of MAb 528 to ErbB1

e) comparing the concentration of soluble epidermal growth factor receptor obtained in step d) with a normal value; and

f) correlating a decrease in the concentration of soluble epidermal growth factor receptor in the biological sample with the presence of an ovarian carcinoma in the patient.

REMARKS

In the March 11, 2004 office action, the Examiner noted that the Section 112 basis of rejection had been overcome with respect to claims 9-23. The Examiner noted that claims 18-23 were objected to but noted that the objection could be overcome with an amendment to those claims to remove the dependency on a rejected claims. The foregoing amendment addresses that basis of rejection placing those claims as they are now in a position for allowance.

Further, in the March 11, 2004 office action, the Examiner also stated that claims 1-8 were allowed. Based on a September 10, 2004 conversation with the Examiner, the indication that those claims were allowed was an error as they were withdrawn. The Examiner further stated that claims 9-17 were rejected based on the arguments in the May 14, and July 29, 2003 office actions. No May 14, 2003 office action exists. Applicants note that May 14, 2003 was Applicants' response to the denial of claims 9-23 which has been deemed acceptable by the Examiner.

With respect to the outstanding bases of rejection for claims 9-17, Applicants respectfully submit that even if the antibody was known, undue experimentation would have been required to achieve the specificity and sensitivity of Applicants' assay.

CONCLUSION

Applicants respectfully submit that the present invention is not obviated by the teachings and that the patent application and claims therein, as amended, are in a condition for allowance. Reconsideration is, therefore, respectfully requested.

Respectfully submitted,

By: _____

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Attorney for Applicant
Telephone No. (412) 561-6250
Facsimile No. (412) 561-6253

Complete Listing of All Claims:

Claim 1 (withdrawn): An isolated nucleic acid selected from the group consisting of:

a) a nucleic acid which encodes a protein comprising the amino acid sequence SEQ ID NO. 1,

b) a nucleic acid which encodes a protein comprising an amino acid sequence which is at least 90% identical to SEQ ID NO. 1 and which has at least 50% of the biological activity of the protein SEQ ID NO. 1,

c) a nucleic acid which is complementary to nucleic acid a) or b).

Claim 2 (withdrawn): The isolated nucleic acid of claim 1 wherein the nucleic acid has the sequence SEQ ID NO. 2.

Claim 3 (withdrawn): The isolated nucleic acid of claim 1 wherein the nucleic acid encodes a protein comprising the amino acid sequence SEQ ID NO. 3.

Claim 4 (withdrawn): The isolated nucleic acid of claim 1 wherein the nucleic acid encodes a protein comprising an amino acid sequence which is at least 99% identical to SEQ ID NO. 1.

Claim 5 (withdrawn): The isolated nucleic acid of claim 4 wherein the encoded protein comprises an amino acid sequence selected from the group consisting of SEQ ID NO. 4, SEQ ID NO. 5, and SEQ ID NO. 6.

Claim 6 (withdrawn): An immunogenic conjugate comprising an immunogenic carrier molecule and a polypeptide of between 10 and 500 amino acids in length comprising an amino acid sequence of 10 to 25 amino acids in length which is identical to an amino acid sequence of the same length contained in an amino acid sequence selected from the group consisting of amino acids 628-705 of SEQ ID NO. 1, amino acids 628-705 of SEQ ID

NO. 4, amino acids 628-705 of SEQ ID NO. 5, and amino acids 628-705 of SEQ ID NO. 6.

Claim 7 (withdrawn): The immunogenic conjugate of claim 6, wherein the polypeptide comprises an amino acid sequence of 11 to 21 amino acids in length which is identical to an amino acid sequence of the same length contained in an amino acid sequence selected from the group consisting of amino acids 628-705 of SEQ ID NO. 1, amino acids 628-705 of SEQ ID NO. 4, amino acids 628-705 of SEQ ID NO. 5, and amino acids 628-705 of SEQ ID NO. 6.

Claim 8 (withdrawn): The immunogenic conjugate of claim 6, wherein the immunogenic carrier molecule is selected from the group consisting of keyhole limpet hemocyanin and bovine serum albumin.

Claim 9 (currently amended): An assay for determining the concentration of ~~soluble~~ epidermal growth factor receptor ~~and full-length epidermal growth factor receptor~~ in a biological sample from a human patient, the assay comprising:

a) obtaining a biological sample from the patient;

b) contacting an amount of a first purified antibody that specifically reacts with a first epitope of the extracellular ligand binding domain of sErbB1 with the patient biological sample to be tested, wherein the first purified antibody is modified with a first labeling moiety;

c) contacting the sample with an amount of a second purified antibody that specifically reacts with a second epitope of the extracellular ligand binding domain of sErbB1, wherein the second purified antibody is modified with a second labeling moiety, and wherein the second purified antibody does not

competitively inhibit the binding of the first purified antibody; and

d) detecting the co-presence of the first and second labels to determine the concentration of the ~~soluble~~ epidermal growth factor receptor complexed with the antibodies; wherein one of the antibodies is chosen from the group consisting of: MAb R.1 and antibodies which competitively inhibit the binding of MAb R.1 to ErbB1; and wherein the other antibody is chosen from the group consisting of MAb 528 and antibodies which competitively inhibit the binding of MAb 528 to ErbB1.

Claim 10 (original): The assay of claim 9 wherein the patient biological sample is chosen from the group consisting of urine and ascites.

Claim 11 (previously amended): The assay of claim 11 wherein the patient biological sample is chosen from the group consisting of blood, serum and plasma.

Claim 12: (original): The assay of claim 11 wherein the first labeling moiety is an affinity binding moiety.

Claim 13 (original): The assay of claim 12 wherein the affinity binding moiety is biotin.

Claim 14 (original): The assay of claim 13 wherein detection of the presence of the first labeling moiety is by binding of the biotin moiety to a solid support coated with a molecule chosen from the group consisting of streptavidin and avidin.

Claim 15 (original): The assay of claim 9 wherein the second labelling moiety is selected from the group consisting of a fluorescent moiety, a colorigenic moiety, and a chemiluminescent moiety.

Claim 16 (original): The assay of claim 9 wherein the second labelling moiety is acridinium.

Claim 17 (original): The assay of claim 16 wherein the detection of the presence of the second labeling moiety is by measuring light emitted from a chemiluminescent reaction utilizing the second labeling moiety.

Claim 18 (amended): ~~The assay of claim 9 wherein the patient is female, further comprising the steps of;~~An assay for determining the concentration of epidermal growth factor receptor in a biological sample from a female patient, the assay comprising:

a) obtaining a biological sample from the ~~patient~~female;

b) contacting an amount of a first purified antibody that specifically reacts with a first epitope of the extracellular ligand binding domain of sErbB1 with the biological sample to be tested, wherein the first purified antibody is modified with a first labeling moiety;

c) contacting the sample with an amount of a second purified antibody that specifically reacts with a second epitope of the extracellular ligand binding domain of SerbB1, wherein the second purified antibody is modified with a second labeling moiety, and wherein the second purified antibody does not competitively inhibit the binding of the first purified antibody;

d) detecting the co-presence of the first and second labels to determine the concentration of the epidermal growth factor receptor complexed with the antibodies; wherein one of the antibodies is chosen from the group consisting of: Mab R.1 and antibodies which competitively inhibit the binding of Mab R.1 to ErbB1; and wherein the other antibody is chosen from the group consisting of Mab 528 and antibodies which competitively inhibit the binding of Mab 528 to ErbB1.

e) comparing the concentration of soluble epidermal growth factor receptor obtained in step d) with a normal value; and

f) correlating a decrease in the concentration of soluble epidermal growth factor receptor in the patient biological sample with the presence of an ovarian carcinoma in the patient.

Claim 19 (original): The assay of claim 18 wherein the normal value is obtained by assaying biological samples from females of approximately the same age as the patient.

Claim 20 (original): The assay of claim 18 further comprising the step of performing a second assay on a biological sample obtained from the patient at a point in time after the initial assay.

Claim 21 (original): The assay of claim 20, wherein the patient has undergone treatment for ovarian cancer selected from the group consisting of chemotherapy, radiation therapy, and surgical treatment in the interval between the initial and second assay.

Claim 22 (original): The assay of claim 20, further comprising the step of correlating an increase in the concentration of soluble epidermal growth factor receptor in the patient biological sample with an improved prognosis in the ovarian cancer condition.

Claim 23 (original): The assay of claim 20, further comprising the step of correlating a decrease in the concentration of soluble epidermal growth factor receptor in the patient biological sample with an declining prognosis in the ovarian cancer condition.